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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,487	08/23/2001	Robert F. Rioux	BSCU-128/00US (28748/325)	1401

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	PAPER NUMBER
3738	
MAIL DATE	DELIVERY MODE
11/10/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/935,487	RIOUX ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,17-20,22 and 24-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,17-20,22 and 24-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,17-20,22,24-29,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beyar et al. (5372600) in view of Mikus et al. (5830179) and Goicoechea (6010530). Beyar et al. disclose a stent for use within a body lumen, col. 3, lines 16-18. It can be seen (Fig. 3) that the stent **17** is a unitarily formed coil segment defining a lumen there through and includes distal, middle and proximal portions. Beyar discloses the coil segment being extendable lengthwise from a first length to an extended length and being compressible lengthwise from the extended length, col. 4, lines 18-38. Beyar et al. does disclose (col. 7, lines 18,19) varying diameter for the stent but does not explicitly state the stent having a distal end of the distal portion and a proximal end of the proximal portion including a diameter greater than a diameter of the middle portion. Regarding claims 1,29,32 it can be seen (Fig. 6) Beyar shows a hook **16** extending lengthwise a direction away from the coil on proximal and distal portions to permit connection to a delivery system **12**. Beyar additionally states the structures for attachment can be **hooks** at both the proximal and distal ends of the coil body for connection to a delivery system, col. 7, lines 8-17. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable

sense. *In re Hutchison*, 69 USPQ 138. The hooks on the ends of the Beyar stent are "adapted for" *connecting* to a delivery system to facilitate winding the coil segment to a reduced width for delivering the coil segment into the body lumen of the patient and *for removing* the coil segment from the body lumen of the patient. Beyar also discloses (col. 6, line 60) coating layers of silicone can be placed on the wire, but does not explicitly state it is placed such that the polymer material encapsulates the coil segment and disposed between the spaced windings of the wound element to form an imperforate flexible webbing. Mikus et al. teach (Fig. 7) a stent with a middle portion between proximal and distal portions that have diameters of the distal and proximal ends respectively of the distal and proximal portions being greater than the middle portion diameter such that the ends aid in anchoring and prevent migration from the vessel, col. 6, lines 23-25,36-39. Goicoechea teaches (Figs. 1,2) a stent **11** which has been encapsulated by a flexible polymer material **12** that encapsulates the coil segment and has an outer **14** and inner layer **15**. It would have been obvious to one of ordinary skill in the art to incorporate larger diameter distal and proximal ends of the distal and proximal portions as taught by Mikus et al. with the coil of Beyar et al. such that it enables the stent to be better anchored when used in a vessel such as the prostatic urethra and migration is prevented. Additionally, it would have been further obvious to one of ordinary skill in the art to incorporate a flexible polymer webbing that encapsulates the stent as taught by Goicoechea with the coil of Beyar et al. as modified with Mikus such that it holds a radiopaque material for enhance visibility, see Goicoechea, col. 4, lines 66,67. With respect to claims 1and 28 limitation of coil

distance, Beyar et al. also discloses the distance between a coil winding of a stent placed in a vessel is at least about 0.5mm or such separation is within the range of about 0.5-10mm , col. 7, lines 5-7. Regarding claims 2,3,25,26 Beyar discloses the wire is biocompatible and can be stainless steel, col. 6, lines 52-60. With respect to claims 4,27 Beyar additionally disclose (col. 6, lines 64-66) the wire cross-section area is in the range of 0.0079 - 0.0071mm^2. With respect to claims 20,22, Beyar discloses the stent is placed in the prostatic urethra before the sphincter, col. 7, lines 62-65 and thus has sufficient strength to maintain an open passageway.

Claims 7,8, 30,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beyar et al. '600 in view of Mikus et al. '179 and Goicoechea '530 as applied to claims 1,24 and further in view of Hachtman et al. (5645559). Beyar et al. in view of Mikus and Goicoechea is explained supra. However, Beyar as modified with Mikus and Goicoechea do not disclose the silicone is a *low durometer* silicone within the range of 0-60D. Hachtman et al. teach that a silicone layer is placed on the stent to provide a barrier that prevents the growth of tissue through the stent and to support the flow of fluid through the lumen, col. 2, lines 14-18. Hachtman et al. also teach that low durometer silicone, such as 30D is placed on a stent, col. 4, lines 49-52. It would have been obvious to one of ordinary skill in the art to use a 30D silicone as taught by Hachtman et al. for the silicone on Beyar et al. wire stent modified with Mikus and Goicoechea such that fluid flow is maintained through the lumen of the device while preventing tissue ingrowth.

Response to Arguments

Applicant's arguments filed 9/9/10 have been fully considered but they are not persuasive. In response to applicant's argument that Beyar is silent that the hooks on the proximal and distal ends of the stent are used to reduce the width of the stent during delivery and removal of the stent, Applicant is reminded a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from

the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Giantureo et al. (5035706) disclose a stent can have means to deliver the stent and remove the stent to reduce the width.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738